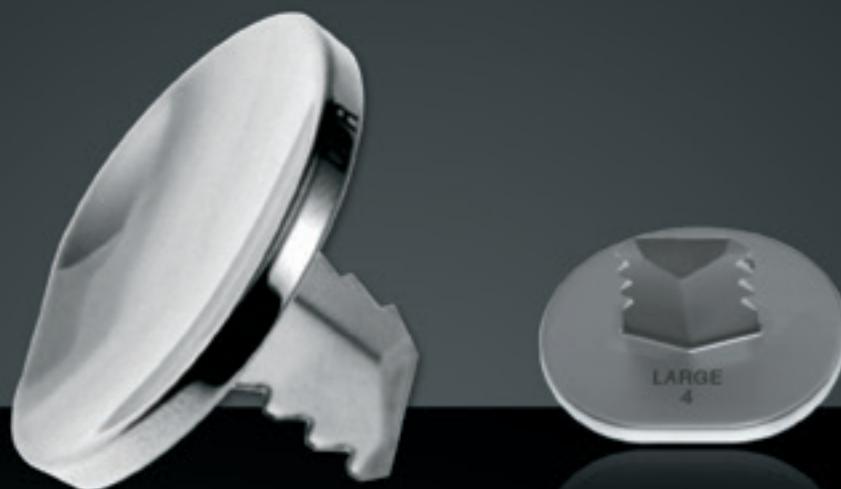


# HEMI

GREAT TOE IMPLANT



## Surgical Technique Guide



*Rethinking Possibilities, Reshaping Lives*



## Indications

The OsteoMed 1st Metatarsal Phalangeal Joint (MTP) Hemi Implant System is intended for use in the treatment of patients with inflammatory arthritis in the first metatarsal joint in the presence of good bone stock and integrity of the first metatarsal head, along with the following clinical conditions: hallux valgus, hallux rigidus and an unstable or painful metatarsophalangeal joint. OsteoMed 1st MTP Joint Hemi Implant System implants are intended for single patient use only.

## Contraindications

Use of the OsteoMed 1st MTP Joint Hemi Implant System is contraindicated in cases of active or suspected infection or in patients who are immunocompromised; in patients previously sensitized to the implant material; in patients with certain metabolic diseases; or in patients exhibiting disorders which would cause the patient to ignore the limitations of artificial joint replacement. This system is further contraindicated in serious systemic diseases. The OsteoMed 1st MTP Joint Hemi Implant System should not be used in cases where the remaining bone is too diminished to provide adequate width or height to surround the implant. Implant failure may occur in cases where there is insufficient available bone or poor bone quality or in patients with blood supply limitations. Use of the implant is further contraindicated in cases of significant angular or biomechanical deformities or in cases which would subject the implants to excessive stress or wear due to patient weight and/or activity level.

## Warnings



The OsteoMed 1st MTP Joint Hemi Implants are not intended to endure excessive functional stresses. Such stresses may lead to accelerated implant wear and/or failure.



Protect Implant surfaces from scratching or other surface damage. Such damage may lead to accelerated implant failure. Avoid direct impact on implants with hammers or other instruments.

# Instructions for Use

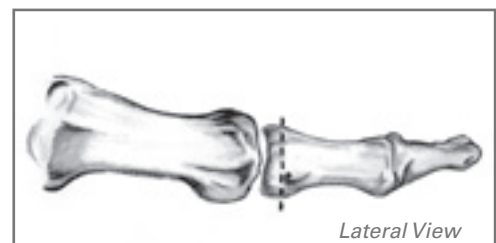
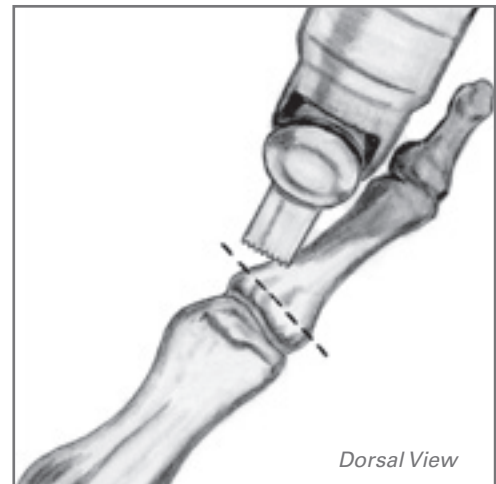
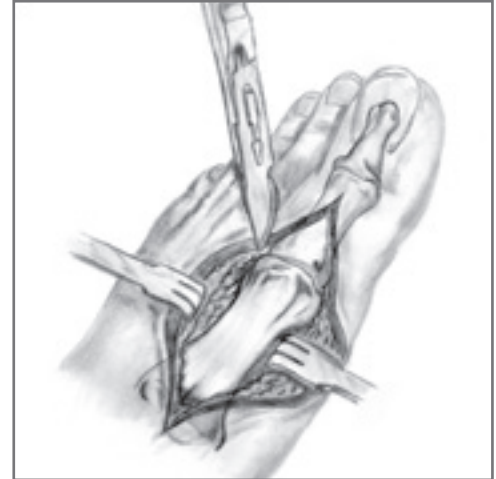
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**1** The 1st Metatarsal Phalangeal Joint is exposed through a 4cm to 5cm dorsal medial incision with appropriate dissection to expose the joint capsule.

**2** The skin is retracted and an incision is made to the bone, in-line with the skin incision. The capsular tissues are carefully dissected from the base of the proximal phalanx and first metatarsal head, on the medial, dorsal, and anterolateral aspect.

**3** Osteophytes are resected completely from the lateral, dorsal, and medial aspects of the metatarsal head to allow normal range of motion. Check motion of the “new” joint for any impingement.

**4** Resect 2mm to 8mm of the articular surface of the phalanx, removing only sufficient bone to avoid prosthetic overspacing and excessive joint tension and to accommodate the thickness of the articulating plate of the implant. The plane of the resection should be parallel to the plane of the concavity of the phalangeal articular surface.

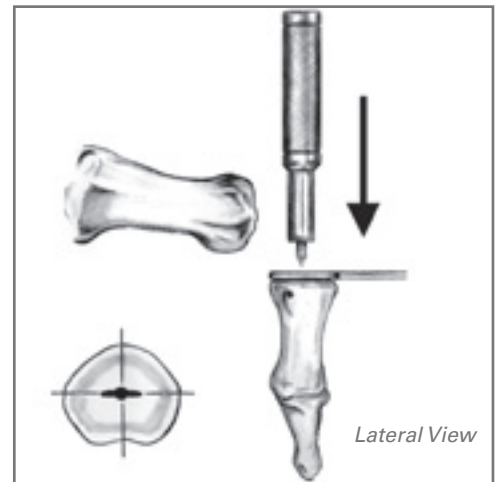


# Instructions for Use

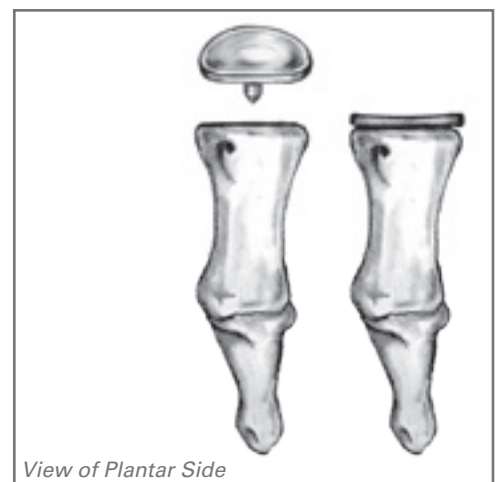
**5** Implant size selection is made using the sizers. Care should be taken to select the size which approximates the dimensions of the osteotomized phalanx and does not extend beyond the margins of the cut surface. Sizers feature a center hole/slot which is used as a guide for the punch instrument.



**6** Using the sizer as a guide, use the punch instrument and a mallet to create a small hole in the center of the bone. The hole will serve to center the instrumentation to assist in placing the implant.



**7** The trial, corresponding to the selected size implant, is then inserted into the phalangeal medullary canal using the impactor and a mallet. The joint is then reduced and is examined for tension and motion. If the joint is too tight, remove the trial and resect an appropriate amount of additional bone from the proximal phalanx. An overly tight joint may result in limited motion and contraction hallux deformity post surgery.



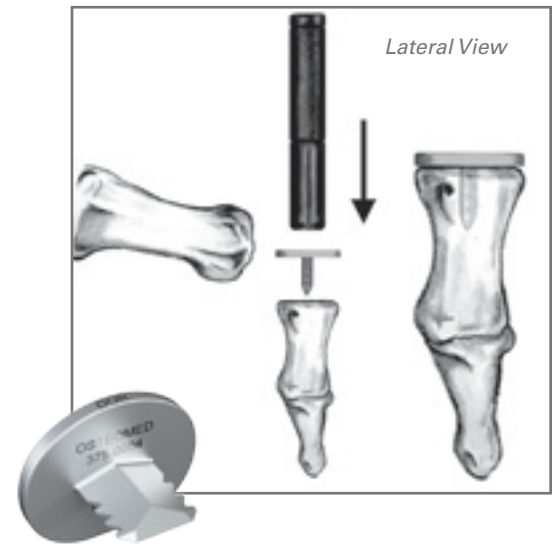
# Instructions for Use

**8** Reinsert the trial and reassess range of motion. A normal range of concentric, unimpinged motion, particularly in dorsiflexion, should be demonstrated. Final remodeling is performed to assure that the entire bone is covered by the implant; the trial is removed.

**9** Once the appropriate size implant is determined and the first metatarsal head remodeled, the implant is fitted into place. Using the impactor, impact the implant until it is flush with the bone.

**10** With all the components implanted, check alignment, range of motion and carefully inspect soft tissue balance. Perform any adjustments if the alignment, range of motion, component fixation, or soft tissue balance is suspect. Remove any debris from the joint space or implant, irrigate, then close using standard closure techniques.

**11** The patient is allowed to ambulate with weight bearing to tolerance on the operated foot within limits imposed by postoperative discomfort, utilizing modified foot gear (a soft bedroom slipper, a postoperative type shoe, or a cutout in a standard shoe). The progression to normal ambulation and the use of standard foot gear is limited only by the persistence of postoperative swelling and discomfort.



*Note: The Hemi great toe implant "DOR" laser mark should be oriented with the dorsal aspect of the proximal phalanx.*

# Instruments



375-0000 Hemi Great Toe Implant Instrument Kit



375-0001 Hemi Great Toe Implant (XS)



375-0009 Implant Trial (XS)



375-0002 Hemi Great Toe Implant (S)



375-0010 Implant Trial (S)



375-0003 Hemi Great Toe Implant (M)



375-0011 Implant Trial (M)



375-0004 Hemi Great Toe Implant (L)



375-0012 Implant Trial (L)



375-0005 Hemi Great Toe Implant Sizer (XS/S)



375-0006 Hemi Great Tom Implant Sizer (M/L)



375-0007 Hemi Great Toe Implant Punch



375-0008 Hemi Great Toe Implant Impactor

# OsteoMed Products



ExtremiFix Headless Cannulated Screws



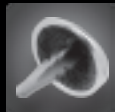
ExtremiFix Cannulated Screws



Large Cannulated Screws



ExtremiFuse



EnCompass



EnCompass Lessers



Hemi



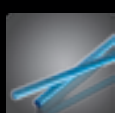
ReFlexion



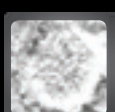
InterPhlex



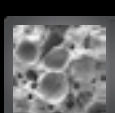
Talar-Fit



Inion



OsteoVationEX



OsteoVation QWIK



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